AUG - 8 2008

K081200

Global Top Inc.

#613, Dreamworld B/D 863-1, Janghang-dong, Ilsandong-gu, Goyang-si
Gyeonggi-do, Korea
Tel: *82-31-9080221 Fax: 082-31-9080224

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: Global Top Inc
#613, Dreamworld B/D 863-1, Janghang-dong,
Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea

Date Summary Prepared: Apr 14, 2008

Contact Person: Jeong Chol, Choi / Director
youdent@naver.com

Device Name:
Trade Name(s): Dental Porcelain (Glass Powder)
Top-Ceram Powder T-1, T1, T2, T3, T4
Classification Name: Porcelain Powder for Clinical Use
Panel: Dental
Product Code: EIH

Predicate Device Information:
K062504 CeraMax marketed by Alphadent Co., Ltd.

Device Description:
Dental Porcelain (Glass Powder) Top-Ceram Powder T-1, T1, T2, T3, T4 are composed of Lanthanum oxide (La2O3), Cerium oxide (CeO2), Titanium xide(TiO2), Silicon dioxide (SiO2), Calcium oxide(CaO), Aluminum oxide(Al2O3), Iron oxide(Fe2O3) and they are intended for use by dental technicians for dental prothesis.

Intended Use:
This device is intended to manufacture dental prosthesis as artificial crown, bridge and dental core

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in intended use and technological characteristics, including:

*components
*indications for use
*chemical properties
*performance properties

Conclusions:
Based on the information provided in this premarket notification Global Top Inc concludes that Dental Porcelain (Glass Powder) Top-Ceram Powder T-1, T1, T2, T3, T4 are safe and effective and substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Global Top, Incorporated
C/O Mr. Claude Yang, CEO
Onbix Corporation
#708 Le-Meilleur Town
837-19 Gangnam-gu
Seoul 135-937
REPUBLIC OF KOREA

AUG - 8 2008

Re: K081200
Trade/Device Names: Top Ceram Powder (T-1, T1, T2, T3, T4)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 7, 2008
Received: July 16, 2008

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081200

Device Name: Top Ceram Powder (T-1, T1, T2, T3, T4)

Indications for Use:

The device is intended to manufacture crown and bridge porcelain-fused-to-metal prostheses and dental cores

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081200